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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,621	07/18/2003	Jan Weber	S63.2-10856-US01	2650

490 7590 05/14/2007
VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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05/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No. 10/622,621	Applicant(s) WEBER ET AL.	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 39-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-38 is/are rejected.
- 7) ☒ Claim(s) 28,30,31 and 33-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>x3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Examiner discussed with Applicants Representative (Walter Steinkraus, Reg# 29,592) on 3/07/2007, the current and pending election restrictions in the case.

Examiner and Applicant's representative came to an agreement to adjust the restriction groups to include claims 27-38 in one group and the other outstanding pending claims in a different group. Examiner has agreed to examine claims 27-38 and withdraw all other outstanding claims.

Claims 1-26 and 39-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/16/2007.

Applicant's election with traverse of the claims 27-38 in the reply filed on 2/16/2007 and the telephonic discussion is acknowledged. The traversal is on the ground(s) that subsequent election restrictions were improper and Applicant did not get chose his elected invention fully. This is not found persuasive because Examiner has telephoned Applicant's Representative to discuss the claims that can be examined in the 604 class and not required to be transferred out of class. Examiner asserts that this has resolved the current restriction traversal.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) that were submitted on 9/29/2003, 3/30/2005 and 6/21/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Claim Objections

Claims 28-31 and 33-38 are objected to because of the following informalities: Examiner requests that Applicant write out all claim limitations and clarify the claimed subject material with regards to the product by process claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-29 and 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al. (6,120,523). Crocker et al. discloses a focalized intraluminal balloon.

Regarding claims 27-29 and 32-37, Crocker et al. discloses a medical balloon (18) having a longitudinal axis and proximal (26) and distal (28) ends, the balloon formed of a polymer material (col 6, ln 25-40), the balloon connecting to a coaxial shaft (37) at a proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof (39), and having a central body wall portion (30) between each

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end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall (38, 42) portions, respectively, wherein the balloon further comprises a lumen (32) extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon (Figures 1-4). Crocker et al. discloses a polymeric balloon that is capable of being radiation cured and is capable of being made of a fluidizable polymer composition, that is comprised of a multi-layer polymeric film (39, 36, 38, 40, 42, 44) wherein a first (39, 48) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 2-3), with a layer comprising an elastomeric band (40, 44) that is stretched during the configuration change.

Claim Rejections - 35 USC § 102

Claims 27-29, 32-35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamlin (6,132,824). Hamlin discloses a multi-layer catheter balloon.

Regarding claims 27-29, 32-35, and 38 Hamlin discloses a medical balloon (40, 58) having a longitudinal axis and proximal (near 64) and distal (near 50) ends, the balloon formed of a polymer material (col 2, ln 30-50), the balloon connecting to a coaxial shaft (50) at a proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof (62), and having a central body wall portion (near 68) between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall (Figures 5-6) portions, respectively, wherein the balloon further comprises a lumen (52) extending longitudinally there through, said lumen passing through the proximal and distal wall portions of the balloon (Figures 5-6).

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Hamlin discloses a polymeric balloon that is capable of being radiation cured and is capable of being made of a fluidizable polymer composition, that is comprised of a multi-layer polymeric film (64, 66, 68) wherein a first (64, 66) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 5-6)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-31 are rejected under 35 U.S.C 103(a) as being unpatentable over Crocker et al. Crocker et al. meets the claim limitations as described above except for the specific embodiment being used in with a stent or with a rapid exchange catheter.

Regarding claims 30-31, Crocker et al. teaches a specific medical balloon structure that is disclosed of being used with rapid exchange and for delivery of stents to the vascular system (col 3, ln 40-70, col 4, ln 40-70, see summary of invention).

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At the time of the invention, it would have been obvious to use the medical balloon as disclosed by the various embodiments and the disclosure of Crocker et al. in order to achieve a versatile controllable balloon element. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Crocker et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: 6,299,595 (see PTO 892).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 5/4/07


Christopher D. Koharski
AU 3763


MATTHEW DeSanto